NOV 0 5 2001

**510K Summary Statement for the
Sciton Inc Image Hair Removal Laser**

k012552

1. General Information

Submitter:	Sciton Inc 845 Commercial Street Palo Alto, CA 94303
Contact Person	Peter Allen
Summary Preparation Date	August 7, 2001

2. Names

Device Names	Image, Image Hair Removal Laser and Image Long Pulse Nd:YAG
Primary Classification Names:	Laser Powered Surgical Instrument for use in General, Plastic Surgery and Dermatolgy in accordance with 21CFR 878-4810.79-GEX

3. Predicated Devices

The product specifications, functionality, indications for use, and treatment parameters of the Sciton Inc Hair Removal Laser are the same or very similar to the following legally market lasers:

Altus Medical, Nd:YAG Aesthetic Laser

Laserscope, Long Pulse Nd:YAG

4. Product Description

The Sciton Inc, Hair Removal Laser is a long pulsed, solid state infrared laser. It is intended to deliver laser energy for use in surgical and aesthetic applications requiring the of Removal of Hair folicles. The Hair Removal Laser produces a beam of infrared light at a wavelength of 1064nm. The system consists of:

A laser console
Internal computer
Control panel and display
Articulated Arm
Footswitch with optional handswitch
Scanner and Handpieces with cooling capability

5. Indications for Use

The Sciton, Inc. Image Hair Removal Laser is intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in general and plastic surgery and dermatology. In addition it is intended to effect stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles (where permanent hair reduction is defined as a long term stable reduction in the number of hairs growing after a treatment regimen)

6. Rationale for Substantial Equivalence

The Sciton Inc Hair Removal Laser shares the same indications for use, similar design features (including wavelength, active medium, cooling system and controls), similar functional features (including pulse duration and fluence), and similar treatment parameters of other marketed long pulse Nd:YAG laser systems (as opposed to Q-switched lasers). Therfore the Sciton Inc Hair Removal Laser is substantially equivalent to the Altus Medical Laser Nd:YAG Aesthetic Laser , Laserscope

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Peter Allen
Director, Regulatory Affairs
Sciton, Inc.
845 Commercial Street
Palo Alto, California 94303

Re: K012552
Trade/Device Name: Sciton Image Hair Removal System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 7, 2001
Received: August 8, 2001

Dear Mr. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, MS

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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FDA Submission Cover Sheet K012552

510(K) Number (if known): K012552

Device Name: Sciton Image Hair Removal Laser

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21CFR 801)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012552